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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/284,233 07/28/99 MEYER

T P564-9008

EXAMINER

HM12/0919

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PARTNER V

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

09/19/01

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.
09/284,233

Applicant(s)
Meyer

Examiner
Portner

Art Unit
1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Aug 22, 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search. (See NOTE below);
- (b) ☐ they raise the issue of new matter. (See NOTE below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☒ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: please see attachment.

4. ☐ Applicant's reply has overcome the following rejection(s): _____
5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).
6. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____
7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):
- Claim(s) allowed: none
- Claim(s) objected to: none
- Claim(s) rejected: 1-11, 13-15, and 17-21
9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner.
10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
11. ☐ Other: _____

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Response to Amendment

1. The amendment After Final submitted August 22, 2001 proposed to amend claim 1 to recite Salmonella. Claim 2 recites a broader scope claim, drawn to any enterobacterial cell and depends from claim 1. The proposed amendment raises a new issue under 35 U.S.C. 112, second paragraph in light of the amendment not canceling claim 2 and was not entered.

2. The Dr. Thomas F. Meyer under 37 CFR 1.132 filed August 22, 2001 is insufficient to overcome the rejection of claims 1-11, 13-15, 17, 19-20 based upon Michetti in view of Russell or Russell in view of Bukanov as set forth in the last Office action because:

The Declaration utilized a strain of Salmonella designated SL3261::YZ222. This strain does not evidence original descriptive support in the instant specification.

Strain SL3261::YZ222 is described to be a Δ thyA strain that contains a stabilized plasmid encoding thyA gene as a means for a balanced lethality to complement the chromosomally deleted thyA. This type of mutant strain is not described in the instant specification.

Three different promoters for expression were utilized, P_{phoP} , P_{nirB} and P_{T7} . Only P_{T7} evidences original descriptive support in the instant specification, description of P_{phoP} , P_{nirB} could not be found in the instant specification.

Four different H.pylori antigens encoded by plasmids in strains CREA 1396, 1398, 1402, 1404, 1412, 1467, 1468. The strains used to immunize a host were not described in the instant specification.

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Of the combinations of expression signals, various antigens and constructs, shown in Exhibit 1, none of the combinations, were described in the instant specification. Of the four antigens encoded on the plasmids, only H.pylori urease and heat shock protein were found in the instant specification. Original descriptive support for HylB and citrate synthase homolog was not found for these two antigens.

The strains that evidenced the fewest colony forming units after challenge were CREA 1467 and 1468, which utilized P_{phoP} , or P_{nirB} promoters, both of which do not evidence original descriptive support in the instant specification. The nirB promoter is known to be induced up to 20 fold under anaerobic conditions (see Goldman et al, 1991, attached hereto).

The Declaration does not present data commensurate in scope with the claimed invention.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

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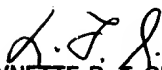
The Group and/or Art Unit location of your application in the PTO will be Group Art

Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

September 18, 2001



LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600